

3

Animal Product
Manual

Reference

Blood and Related By-Products

Contents

Introduction	page 3-3-1
Locator	page 3-3-2
Blood for Scientific Use or Research	page 3-3-3
Blood for Pharmaceutical Use	page 3-3-5
Dried Blood Products Not Fully Rendered	page 3-3-6

Introduction

The *Blood and Related By-Products* section covers fractions (parts) of blood imported for pharmaceutical or scientific use (includes biological research and diagnostic testing). Examples of blood fractions regulated for scientific use are listed under [Blood for Scientific Use or Research on page 3-3-3](#).

Also covered under this section are dried blood products such as spray dried blood and spray dried plasma. **Do not** consider these products rendered; regulate them under this section. These products have **not** been subjected to high temperatures long enough to inactivate exotic animal disease agents. Dried blood products are used as a protein supplement in livestock feed and are used to increase the palatability of foods for dogs and cats.

Blood importations or their fractions drawn from avian (bird), equine (horse), ruminant, or swine from any country require a VS permit authorizing entry. If the importation is human or non-human primate blood or its fractions, advise the shipper to contact the Public Health Service of the Department of Health and Human Services (PHS). This Agency regulates such products.

Not covered in this section are rendered blood products such as blood meal imported for animal feed or fertilizer. Regulate these products under [Animal Waste and Related By-Products](#).


When a VS permit authorizes entry of the blood or related by-product, match the shipping documents with the information on the permit that follows:

- ◆ Current date
- ◆ Description of the material
- ◆ Shipper

- ◆ Consignee
- ◆ Conditions spelled out on the permit

Follow **Table 3-3-1** as you match the permit with the shipping documents.

TABLE 3-3-1 Validate Importation Authorized Entry by a VS Permit

If the shipping documents:	And the:	Then:
Match the permit		RELEASE or CONTROL as stated on the permit
Do not match the permit	Permit has expired	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. HAVE the consignee contact VS, TTSPS (see page 2-4-25) 3. SAFEGUARD the importation until you hear from VS, TTSPS
	Discrepancy is other than an expired permit	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)

Locator

When a VS permit does **not** accompany an importation of blood, blood fraction, or related by-product, use **Table 3-3-2** to determine the appropriate regulatory action to take.

TABLE 3-3-2 Where to Find Regulatory Action on Blood and Related By-Products Not Authorized by a VS Permit

If the importation is imported for:	Then:
Scientific use or research (e.g., antibodies, antigens, albumin, blood, plasma, serum)	GO to Table 3-3-3
Pharmaceutical use (products usually for manufacturing cosmetics ¹ , human nutritional supplements, and test kit components)	GO to Table 3-3-5
Veterinary biological use (also called veterinary biologics) are those used for the diagnosis and treatment of diseases in animals including vaccines, bacterins, antitoxins, toxoids, immunomodulators	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. ADVISE the importer of the hold because the importation requires a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including applying for a veterinary biological product permit issued by VS, CVB (see page 2-4-25)
Animal feed (protein supplement; not fully rendered)	GO to Table 3-3-6

- 1 If the product is an ingredient in a cosmetic that is in final, finished packaging and ready for sale, then the cosmetic is **unrestricted**. However, if the product is a bulk component to be incorporated into cosmetics, then continue to [Table 3-3-5](#).

Blood for Scientific Use or Research

Fractions (parts) of blood may be imported for research or diagnostic testing. The products are usually liquid, but can be imported as a powder. They are shipped in small quantities. Usually, if the importation is a liquid, there is less than 200 milliliters; if it is a powder, it is in small vials. Following are examples of blood fractions imported for research or diagnostic testing.

- ◆ Albumin
- ◆ Antibodies
- ◆ Antiserum
- ◆ Blood clotting factors
- ◆ Leukocytes (white blood cells)
- ◆ Plasma
- ◆ Red blood cells
- ◆ Serum
- ◆ Whole blood



Some blood products are highly perishable. Therefore, expedite an importation when you are authorized to release it. If you cannot release the hold, allow the importer to apply dry ice or refrigerate the by-product.

Continue on to [Table 3-3-3](#).

TABLE 3-3-3 Regulatory Action on Blood and Blood Fractions Imported for Scientific Use or Research

If the blood fraction is:	And was collected from:	And is:	Then:
One specifically listed below: <ul style="list-style-type: none"> ◆ Albumin ◆ Antibodies ◆ Antiserum ◆ Blood clotting factors ◆ Leukocytes (white blood cells) ◆ Plasma ◆ Red blood cells ◆ Serum¹ ◆ Whole blood 	<ul style="list-style-type: none"> ◆ Birds ◆ Equine (horses) ◆ Poultry ◆ Ruminants ◆ Swine 	→	1. DO NOT RELEASE the HOLD 2. ADVISE the importer of the hold because the importation requires a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including applying for a VS permit (see page 2-4-25)
	<ul style="list-style-type: none"> ◆ Amphibians ◆ Laboratory mammals (rats, mice, gerbils, hamsters, guinea pigs, rabbits) ◆ Marine mammals ◆ Reptiles 	Less than one liter	GO to Table 3-3-4
		One liter or more	1. HAVE importer contact VS, TTSPS 2. REFER to VS, TTSPS on page H-1-3 for VS contacts in TTSPS
	<ul style="list-style-type: none"> ◆ Canines (dogs) ◆ Felines (cats) ◆ Fish ◆ Humans ◆ Non-human primates (apes, lemurs, monkeys) 	→	GO to Table 3-3-4
Not specifically listed above		→	1. DO NOT RELEASE the HOLD 2. ADVISE the importer of the hold because the importation may require a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including apply for a VS permit (see page 2-4-25)

¹ Includes adult and fetal bovine serum.

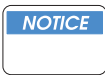
TABLE 3-3-4 Regulatory Action on Specified Blood Fractions from Canines, Felines, Humans, Laboratory Animals, Marine Mammals, or Non-human Primates Imported for Research or Scientific Use

If the blood fraction originated from:	And is accompanied by a declaration from the producer or shipper that:	Then:
<ul style="list-style-type: none"> ◆ Canines (dogs) ◆ Felines (cats) ◆ Humans ◆ Non-human primates (apes, lemurs, monkeys) 	1. Provides a description of the material as canine, feline, human, or non-human primate as applicable 2. The animals were neither inoculated with nor exposed to infectious agents of agricultural concern including zoonotic agents 3. The material contains no other animal or non-human primate material	RELEASE
	Lacks the declaration as described above	DO NOT RELEASE the HOLD until the producer or shipper provides the required statement
<ul style="list-style-type: none"> ◆ Laboratory animals including gerbils, guinea pigs, hamsters, mice, rabbits, and rats 	1. Provides a description of the material and the species from which the fraction was derived, AND 2. States that the animals (a) were not exposed to or inoculated with any exotic livestock/avian disease agent, and (b) did not originated from a facility where work with exotic livestock/avian disease agents is conducted	RELEASE
	Lacks the declaration as described directly above	DO NOT RELEASE the HOLD until the producer or shipper provides the required statement
<ul style="list-style-type: none"> ◆ Amphibians ◆ Fishes ◆ Marine mammals ◆ Reptiles 	Provides a description of the material	RELEASE
	Lacks the declaration as described directly above	DO NOT RELEASE the HOLD until the producer or shipper provides the required statement

Blood for Pharmaceutical Use

Blood and fractions of blood may be imported for pharmaceutical use. Such uses include manufacturing cosmetics, drugs, medicines, and human nutritional supplements. Blood fractions for pharmaceutical use are usually imported in bulk and can be in the form of a liquid, a powder, or a paste. Usually if the importation is a liquid, there is more

than a liter; if the importation is a powder, there is more than a gram. However, the blood or blood fraction may also be imported in pre-filled vials or containers of varying sizes. Continue on to [Table 3-3-5](#).



Some blood products are highly perishable. Therefore, expedite an importation when you are authorized to release it. If you cannot release the hold, allow the importer to apply dry ice or refrigerate the by-product.



TABLE 3-3-5 Regulatory Action on Blood Imported for Pharmaceutical Use

If the blood or blood fraction was derived from:	And the country of origin is known to be:	Then:
Ruminants	Affected with BSE	1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ (see Appendix H)
	Free from BSE	1. DO NOT RELEASE the HOLD 2. ADVISE the importer of the hold that the importation requires a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including apply for a VS permit (see page 2-4-25)
Birds or poultry		1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel (see Appendix H)
Equine (horses)		
Swine		
Unknown animal		1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel (see Appendix H)

Dried Blood Products Not Fully Rendered

Dried blood products not fully rendered are **not** subjected to high temperatures long enough to inactivate exotic animal disease agents. Such dried blood products may be used as a protein supplement in livestock feed and to increase the palatability of pet food. Continue on to [Table 3-3-6](#).

TABLE 3-3-6 Action on Dried Blood Products Not Fully Rendered

If the blood or blood fraction was derived from:	And the country of origin is known to be:	Then:
Ruminants	Affected with BSE	1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel (see Appendix H)
	Free from BSE	1. DO NOT RELEASE the HOLD 2. ADVISE the importer of the hold that the importation requires a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including apply for a VS permit (see page 2-4-25)
Birds		
Equines (horses)		
Poultry		
Swine		1. REFUSE ENTRY 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel (see Appendix H)
Unknown animal		

